

REMARKS/ARGUMENTS

Claims 1-7,10,11,13-16,19-23,25-27,29-34 and 38 are pending in the present Application. Applicants request reconsideration in view of the following.

Claims 1-7,10-11,13-14,19-23,25-27,29-32, and 38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,559,189 to Baker, Jr. et al. (Baker).

Baker is directed to compositions and methods for decreasing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms and viruses. Primarily, the Baker invention comprises oil-in-water emulsion compositions and methods for decontaminating a sample with such emulsion compositions.

Claim 1 recites a tampon comprising an absorbent material and a composition disposed in the absorbent material. The composition has at least one antibacterial agent in an amount of about 0.01 wt.% to about 5 wt.% and at least one finishing agent in an amount of about 0.01 wt.% to about 10 wt.% of the total weight of the tampon. The composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth.

Applicants respectfully submit that Baker does not render claim 1 obvious under 35 U.S.C. § 103 (a) because Baker fails to disclose or suggest each and every element of claim 1.

As conceded by the Action, Baker fails to disclose or suggest a specific amount of anti-bacterial agent, namely from about 0.01 wt.% to about 5 wt.%, effective to neutralize the production of TSST-1 toxin based on the total weight of the

tampon. As further conceded by the Action, Baker also fails to disclose or suggest a specific amount of finishing agent, namely from about 0.01 wt.% to about 10 wt.%, based on the total weight of the tampon. Moreover, nowhere in Baker is the neutralization of TSST-1 toxin remotely disclosed or suggested. Without specific disclosure of the these claimed features, it is not surprising that Baker also fails to provide any motivation for an accompanying synergistic effect of antibacterial properties within any range of claim 1 disclosed by Applicants' invention. For purposes of obviousness under § 103, the motivation to combine these features in the specific amounts to arrive at a synergistic effect must come from the prior art. As the USPTO Board of Patent Appeals and Interference stated in the case of Ex parte Obukowicz, 27 USPQ2d 1063 (1992), a prior art reference that only gives general guidance and is not at all specific as to the particular form of the claimed invention and how to achieve it may make the approach, "obvious to try" but does not make the claimed invention obvious, citing In re O'Farrell, 853 F.2d 894, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988). Baker is such a prior art reference.

As noted above, Baker discloses an overly broad genus of oil-in-water emulsion compositions and ingredients (col. 28, line 42–col. 31, line 67). This listing of compositions fails to demonstrate that Baker was in possession of the specifically recited features, or species of Applicants' invention. Namely, the antibacterial and finishing agents in the amounts described based on the total weight of the tampon. Baker not only fails to show how a person of ordinary skill can specifically select these elements recited by Applicants' claims from Baker's listed ingredients without undue experimentation, Baker also fails to even contemplate the need for specifically selecting these elements recited by Applicants' claims to achieve the synergistic effects of the present invention. It has been recognized that where a prior art genus contains a small number of members, this does not create a prima facie rule of obviousness. Some motivation to select the claimed species or subgenus must be taught by the prior art. In re Deuel, 51 F.3d at 1558-59, 34 U.S.P.Q. at 1215. (Fed. Circ. 1995).

Furthermore, the Action's conclusion that it would have been obvious to a person of ordinary skill in the art to discover optimum working ranges for both the antibacterial agent and finishing agent, based on the total weight of the tampon, is unsupported by sufficient reasoning or logic to lead a person of ordinary skill to Applicants' claim 1. The absence of this reasoning indicates that the Action impermissibly relied on Applicants' claim 1 in hindsight to reach an obviousness conclusion. Moreover, while arguably optimum ranges have been recognized to be within the purview of a person of ordinary skill in the art, a prima facie case based on this recognition is limited to conditions where the ranges at issue are the only difference between the claims. In re Aller, 220 F.2d 454, 456, 205 U.S.P.Q. 233 235 (CCPA 1955). As noted above, not only does Baker fail to disclose each and every element of claim 1, Baker also fails to provide motivation for the selection of a specific amount of antibacterial-surfactant combination or suggest how a combination of the two ingredients, based on the total weight of the tampon, may produce a synergistic effect.

The Action further rejected claims 20-23, 25-27, 29-32, and 38 under 35 U.S.C. 103 (a) in view of Baker.

Independent claim 20 recites a method of inhibiting the production of TSST-1 toxin by exposing TSST-1 toxin-producing *Staphylococcus aureus* bacteria to a tampon having an absorbent material and a composition comprising at least one antibacterial agent in an amount of about 0.01 wt.% to about 5 wt.% of the total weight of the tampon and at least one finishing agent in an amount of about 0.01 wt.% to about 10 wt.% of the total weight of the tampon. The composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduces *Staphylococcus aureus* bacteria growth.

Baker is summarized above. Applicants submit that Baker fails to disclose all the elements of Applicants' claim 20. Specifically, as conceded by the Action, Baker fails to disclose or suggest a method of inhibiting the production of TSST-1 toxin by exposing *Staphylococcus aureus* bacteria to a tampon having an absorbent material, and a composition comprising at least one antibacterial, and finishing agent based on the total weight of the tampon in the specific amounts recited by Applicants' claim 20. Baker also fails to disclose any synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin to reduce *S. Aureus* bacterial growth. Moreover, as stated above, Baker discloses a broad genus of oil-in-water compositions, but fails to provide any motivation to specifically select an antibacterial agent or finishing agent in the amounts recited by Applicants' claim 20.

Furthermore, contrary to the Action's assertion, a skilled artisan would have little success at arriving to Applicants' disclosed ranges of both the anti-bacterial and finishing agents recited by Applicants' claims, since the differences between Applicants' claims and Baker are not limited to the disclosed ranges. Rather, Baker fails to also disclose how a skilled artisan would specifically select the antibacterial and finishing agent, based on total tampon weight, to reach any subsequent synergistic effect recited by Applicants' claim 20.

Accordingly, for at least the reasons set forth above, Applicants respectfully submit that Baker fails to render obvious claims 1-7,10-11,13-14,19-23,25-27,29-32, and 38.

Claims 15-16 and 33-34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Baker, in view of U.S. Patent No. 6,335,012 to Fischetti et al.

Claims 15 and 16 indirectly depend from claim 1. Claims 33 and 34 depend indirectly from independent claim 20. Claims 15 and 33 recite a tampon with one or more polyoxyethylene fatty acid esters as nonionic surfactants. Claims 16 and 34

add the feature that the polyoxyethylene fatty acid ester is present in an amount about 2.5 wt.%, based on the total weight of the tampon.

Baker is summarized above. Fischetti is directed to a method of treating bacterial dental caries by delivering a composition of an effective amount of lytic enzyme to the mouth, gums and teeth via a carrier. The lytic enzyme is capable of digesting bacterial cell walls.

As delineated above, Baker fails to render obvious claims 1 and 20. Applicants respectfully submit that Fischetti fails to cure the deficiencies of Baker because Fischetti also fails to disclose or suggest each and every element of claims 1 and 20, namely at least one antibacterial agent in an amount of about 0.01 wt.% to about 5 wt.% of the total weight of the tampon; and at least one finishing agent in an amount of about 0.01 wt.% to about 10 wt.% of the total weight of the tampon, wherein the composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth.

Additional, the Action notes that Fischetti discloses a polyoxyethylene sorbital ester (col. 11, lines 14-16), and the Action takes official notice of the equivalence of polyoxyethelene fatty acid ester and polyoxyethylene sorbital ester for their use as surfactants in tampons. The Action further notes that the selection of these equivalents would be within the level of ordinary skill in the art. Applicants respectfully reassert that, in this respect, the Action improperly relies on the level of ordinary skill in the art as a source of motivation to suggest the limitations of Applicants' claims 1 and 20.

The Action must provide some objective reason to combine the references. Neither Baker nor Fischetti suggests the substitution of one ester for the other, alone or in combination, with a specific amount of antibacterial based on the total weight of the tampon as recited by claims 1 and 20. Furthermore, the requirement for this

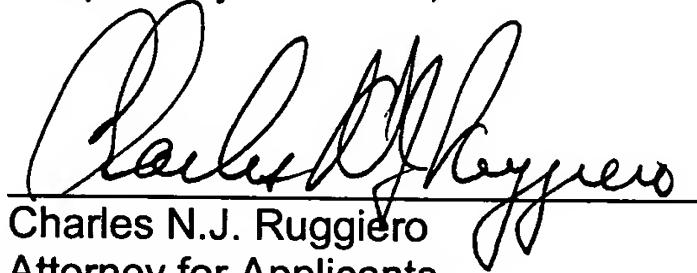
motivation is not cured by taking official notice of equivalent properties between the esters because this notice merely acknowledges similarities in properties of the esters, not motivation to substitute one for the other.

Therefore, since neither Baker nor Fischetti, taken alone or in combination, discloses or suggests all the claimed features recited in claims 1 and 20, Applicants respectfully submit that claims 15,16, 33 and 34, which are indirectly dependent therefrom, are patentably distinguishable over either reference, taken alone or in combination. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 15, 16, 33 and 34 under 35 U.S.C. § 103(a).

In view of the foregoing, Applicants respectfully submit that all claims presented in this application are patentably distinguishable over the cited art, taken alone or in combination, and request favorable consideration and the passage of the application to allowance.

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Respectfully submitted,



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